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Subject: Environmental Defense comments on Acetyltributyl Citrate (CAS# 77-90-7)

(Submitted via Internet 7/13/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and skennedy@morflex.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Acetyltributyl Citrate (CAS# 77-90-7).

Morflex, Inc., in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted robust summaries and a test plan describing data to address SIDS elements required for acetyltributyl citrate (ATBC). According to the test plan, this chemical is used as a plasticizer with numerous aqueous- and solvent-based polymers. These polymers find uses in medicinal plastics and food contact products as well as products ranging from children's toys to nitrocellulose-based explosives and propellants. Thus, there is considerable potential for its release into the environment and for human contact. Data presented for ATBC suggest it presents a low hazard to human health, but it does have appreciable toxicity to aquatic organisms.

The concise test plan presents a matrix of SIDS elements required by the HPV Challenge versus available data. According to this matrix, data are available to address each of the required SIDS elements. Review of the test plan and extensive supporting robust summaries indicates most of the elements for chemical/physical properties, environmental fate and ecotoxicity have been addressed through actual studies, and all have also been estimated by computer models. The modeled data compare favorably with those obtained through actual studies. Thus, even though the purity of the test compound is not provided in some of the older studies in which these data were determined, we consider the respective SIDS elements to have been adequately addressed. These studies and estimations indicate that ATBC has some potential to bioaccumulate and exhibits appreciable toxicity to aquatic organisms.

Review of the human health-related data indicates that ATBC has low acute or repeated toxicity to mammals, is not genotoxic and has low potential for reproductive/developmental toxicity. On review of the robust summaries, we note that many of the studies indicate the purity of the test chemical is "not stated" and then in parentheses indicate "(99% minimum specification)." We assume that this notation means the material tested was pure, but that is not immediately clear. We also note that the robust summaries describe many older studies that were not conducted under GLP and do not provide the purity of the chemical tested. With the exception of the LD50 studies, results of these studies are supported by more recent, well-designed studies that were conducted under GLP; thus, we would question the need to include the older studies. Also, the low toxicity of ATBC observed in the repeated dose studies indicates there is no need for additional LD50 studies.

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In summary, this submission appears to be complete and acceptable to meet the requirements of the HPV Challenge.

Thank you for this opportunity to comment.

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